IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAS) PRODUCTS LIABILITY LITIGATION	:	**CIVIL ACTION**
	:	**MDL No. 3094** **24-md-3094**
THIS DOCUMENT RELATES TO:	:	**HON. KAREN SPENCER MARSTON**
ALL ACTIONS/ALL CASES	:	**Filed Conditionally Under Seal Pursuant to Order Re: Filing Documents Under Seal ECF 187-2**

PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION TO SUPPLEMENT THE RECORD AS TO CROSS CUTTING ISSUE NO. 1

INTRODUCTION

Lilly urges this Court to believe that its October 2, 2023 submission to the FDA described a method of diagnosing gastroparesis that was not reliable, [redacted]. [redacted].

[redacted].

LEGAL STANDARD

Courts generally grant motions to supplement the record where there is no prejudice to the opposing party. *See U.S. ex. rel. Feldstein v. Organon, Inc.*, 2009 WL 961267, at *3 (D.N.J. April 7, 2009); *see also Hamer v. City of Trinidad*, 441 F. Supp. 3d 1155 (D. Colo. 2020) (granting motion to supplement the record with relevant materials "for the sake of completeness to ensure proper consideration of the issues presented[.]"); *Columbia Gas Transmission, LLC v. Haas*, 341 F. Supp. 3d 607, 613 (D. Md. 2018) (granting motion to supplement record where there was no prejudice to opposing party because it had notice of the request for supplementation and an opportunity to submit contrary evidence). Courts "look favorably on efforts to supplement the record absent prejudice or bad faith." *Phoenix Light SF Ltd. v. Deutsche Bank Nat'l Tr. Co.*, 585 F. Supp. 3d 540, 568 n.21 (S.D.N.Y. 2022), *aff'd sub nom. Phoenix Light SF Ltd. v. Bank of New York Mellon*, 66 F.4th 365 (2d Cir. 2023) (citing *Katz v. Metro. Transp. Auth.*, 2017 WL 6734185, at *12 (E.D.N.Y. Dec. 29, 2017) (collecting cases)).

While Lilly urges the Court to apply Rule 16(b)(4)'s "good cause" standard, Lilly does not cite any case where a court has applied that standard to a motion to supplement the record. Instead, Lilly cites cases involving modification of schedules. However, Plaintiffs do not seek modification of a schedule. For example, Lilly cites *Shrieves v. Philadelphia Facilities Management Corp.,* 2020 WL 7240450 (E.D. Pa. Dec. 8, 2020), which is distinguishable, as *Shrieves* was a ruling on a motion for leave to file a second amended complaint. Even if Rule 16(b)(4)'s "good cause" standard applies, as Lilly urges, the standard is met and the Court should consider Lilly's regulatory submission. *See Shrieves,* 2020 WL 7240450, at *5 ("'[T]he court may modify the schedule on a showing of good cause if it cannot reasonably be met despite the diligence of the party seeking the

extension.'" (quoting Fed. R. Civ. P. 16, advisory committee's note to the 1983 amendment)). Because Plaintiffs have been diligent, "good cause" is shown.

ARGUMENT

1. [redacted].[1] In Plaintiffs' interrogatories pertaining to Issue No. 1, Plaintiffs asked Lilly to identify "each test or method that [Lilly] contend[s] is a reliable basis for the diagnosis of gastroparesis."[2] In response, [redacted]

[1] The fact that Lilly has found literature that is consistent with its litigation position or that certain statements in the October 2, 2023, FDA submission are consistent with Lilly's litigation position *does not* render the flagged statement [redacted] *consistent* with Lilly's litigation position. Further, Lilly's insistence that "gastric emptying" must be evaluated misses the point that [redacted] whereas it has told the Court the opposite.

[2] Exhibit A: Lilly's Responses and Objections to Plaintiffs' First Set of Interrogatories at 3 (Sept. 13, 2024).

[3] Exhibit A: Lilly's Responses and Objections to Plaintiffs' First Set of Interrogatories at 3-5 (Sept. 13, 2024).

[4] *See* Exhibit 1 to Plaintiffs' Motion to Supplement the Record at LLY-GLPMDL-08233982. Lilly's representation to the FDA was not some passing or off-hand reference by a low-level employee. [redacted]

[redacted][5]

Lilly's claim that its position is unchanged is not based on any reasonable reading of its regulatory submission.

For these reasons, contrary to Lilly's arguments, this is an appropriate case for application of regulatory estoppel. *See Brian Handel D.M.D., P.C. v. Allstate Ins. Co.,* 499 F.Supp.3d 95, 100-101 (E.D. Pa. 2020) ("Regulatory estoppel prohibits parties from switching legal positions to suit their own ends." (quotations omitted)) (citing *Simon Wrecking Co. v. AIU Ins. Co.,* 541 F. Supp. 2d 714, 717 (E.D. Pa. 2008)).[6] However, even if estoppel does not apply, the Court should consider Lilly's October 2, 2023 FDA submission, as it is direct evidence of how major pharmaceutical companies and regulators view the issue of diagnosing gastroparesis.

2. Plaintiffs diligently and promptly sought to supplement the record once becoming aware of the significance of the document at issue.

Lilly's opposition does not even attempt to argue that prejudice would result from the Court's consideration of Lilly's documents, because there is no conceivable prejudice to Lilly. Lilly provides no authority supporting the rejection of a document proffered in support of a pending motion and instead misguidedly attempts to recast requests to amend pleadings, add parties, and file late motions, as if they were analogous. It is within the Court's discretion to review this relevant submission, and Lilly has identified no prejudice that would result, or authority that would weigh in favor of exclusion.

[redacted]

[5] *See* Exhibit B: Transcript of Oral Argument held May 20, 2025, at 21-24.

[6] *See Sunbeam Corp. v. Liberty Mut. Ins. Co.,* 781 A.2d 1189, 1192 (Pa. 2001) ("In essence, the doctrine prohibits parties from switching legal positions to suit their own ends.").

Lilly's focus on Plaintiff's review of Defendants' massive productions misses the mark, and minimizes the herculean undertaking that is document review in an MDL such as this.[7] The document at issue here was part of a production of more than 19,000 documents totaling 635,239 pages. At the time Lilly produced the subject document in September 2024, Plaintiffs were already in the process of reviewing 174,417 documents recently produced by the Defendants, totaling 17,963,035 pages. To date, Lilly alone has produced 353,036 documents totaling 18,321,277 pages. Any suggestion that it was Plaintiff's obligation, as opposed to Lilly's, to be candid with the Court about Lilly's representations to the FDA, is unreasonable, and arguments that Plaintiffs should have identified the document at issue sooner are inapposite. Indeed, Plaintiffs' Co-Lead Counsel moved to supplement the record the very day Plaintiffs' counsel realized the significance of the document at issue.

3. This Court should exercise its discretion to consider the document at issue.

Here, as explained above, the circumstances involve the review of a massive number of documents involving complex issues. Simply put, Plaintiffs have moved with all possible haste to find the document at issue and bring it to the Court's attention. Second, the document at issue, particularly the portion quoted in Plaintiffs' Motion, is highly probative to Issue No. 1. [redacted]

[7] For example, Lilly cites *Doe v. Hosp. of Univ. of Pennsylvania,* 2021 WL 2671791, at *9 n.10 (E.D. Pa. June 29, 2021) for the proposition that a party cannot supplement the record with documents received prior to an applicable deadline. However, *Doe* is clearly distinguishable, as the motion at issue was a motion for leave to file a second amended complaint, not a motion to supplement the record. Further, the documents that formed the basis of the dilatory plaintiff's request for leave were merely based on defendants' initial disclosures and a Rule 26(f) report. *Id.* Unlike *Doe,* Plaintiffs here were tasked with reviewing hundreds of thousands of documents totaling more than eighteen millions pages of corporate material, a far cry from the two litigation documents in *Doe*.

[redacted]. Most importantly, Lilly does not—and cannot—show that it is in any way prejudiced by the Court's consideration of Lilly's own regulatory submission. Indeed, "the parties will be best served by the Court deciding the issues presented to it on the most complete factual basis possible." *Phoenix Light SF Ltd*, 585 F. Supp. 3d at 568 n.21.

CONCLUSION

For the foregoing reasons, as well as those set forth in Plaintiffs' Motion to Supplement the Record, Plaintiffs respectfully request that Exhibit 1 to Plaintiffs' Motion to supplement the record be considered by the Court determining Issue No. 1.

Dated: July 28, 2025

Respectfully submitted,

/s/ Paul J. Pennock

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CERTIFICATE OF SERVICE

I hereby certify that on July 28, 2025, a true and correct copy of the foregoing document was electronically filed using the Court's CM/ECF System, which will send notification of such filing to all counsel of record.

/s/ Paul J. Pennock
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